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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,399	11/02/2001	Caili Wang	13403.0005.NPUS00	8585

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

### Application No.

10/033,399

### Applicant(s)

WANG ET AL.

### Examiner

Gerald G Leffers Jr., PhD

### Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 3,8,9,23,28,29 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,10-22,24-27,30-45 and 47-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                                |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/20/2002</u> . | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-2, 4-7, 10-22, 24-27, 30-45 and 47-76 directed to viral display systems) in the response filed 9/25/2003 is acknowledged. Claims 1-76 are pending in the instant application, with claims 3, 8-9, 23, 28-29 and 46 withdrawn from consideration as being directed to nonelected inventions. Claims 1-2, 4-7, 10-22, 24-27, 30-45 and 47-76 are under consideration.

### ***Information Disclosure Statement***

Receipt is acknowledged of an information disclosure statement (IDS), filed on 5/20/2002. The signed and initialed PTO Form 1449 has been mailed with this action.

### ***Claim Objections***

Claims 1, 21, 41 and 62 (and various dependent claims) are objected to because of the following informalities: each of the claims remains directed to nonelected embodiments of the claimed invention. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-2, 4-5, 10-18, 21-22, 24-25, 30-45, 47-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Each of the rejected claims is directed to an adapter display system where an exogenous polypeptide is displayed on the surface of a “genetic package” via the non-covalent interaction of a pair of fusion polypeptides comprising adapter sequences that interact with one another in a pair-wise manner and where one of the two fusion protein is functionally displayed on the surface of the genetic package. The specification teaches that the genetic package can include such diverse products as, for example, bacterial cells, phage or viral particles and bacterial spores. As such, the claimed invention encompasses an enormous genus of genetic packages that must be able to display at least one of their surface proteins as part of a fusion polypeptide so as to allow interaction between a particular “adapter” and its binding partner. Functionally, this encompasses the operative linkage of a heterologous protein sequence into a surface protein such that the genetic package can assemble properly and yet maintain display of the adapter in a functional manner. Thus, the claimed invention encompasses an enormous number of specific embodiments that must retain the ability to assemble and functionally display a fusion polypeptide from the surface of the genetic package.

The instant specification provide an embodiment where filamentous phage are used to exemplify the use of a pair of adapter sequences for functional display of a polypeptide that provides enormous flexibility with regard to what is displayed on the surface of the phage. The

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system used, filamentous phage, is the most well characterized phage display system and provides a ready platform for the system described by applicants. The exemplified embodiment, however, does not provide the skilled artisan a framework to envision a sufficient number of specific embodiments to describe the broadly claimed genus of genetic packages, even for the elected embodiment of viral genetic packages. Viral display systems have only been developed for a limited number of different phage and viruses using only a limited number of surface proteins. In order to envision a sufficient number of embodiments to describe the broadly claimed genus, the skilled artisan would have to first be able to envision a particular phage or viral protein that would necessarily be able to incorporate a heterologous protein in such a way so as to retain the ability to form a part of the genetic package and also retain the ability to functionally display the “adapter” needed to practice the claimed invention. Given the tremendous variety among the different viruses encompassed by the claims (e.g. TMV, HIV, ssDNA phages, dsDNA phages, etc.), it would be unpredictable for the skilled artisan to envision those specific embodiments that meet the functional requirements of the claims. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the broadly claimed genus of genetic packages, vectors encoding adapter-fusions for use in displaying the desired polypeptide and the methods of use thereof.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-2, 4-7, 10-20, 41-45, 47-61, 65-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 41 are vague and indefinite in that the metes and bounds of the phrase "...the vector is devoid of outer-surface sequences encoding any functional outer-surface proteins of the genetic package..." are unclear. It is unclear whether the vector can comprise *any* sequence derived from a gene encoding an outersurface protein so long as the encoded protein is not functional (e.g. a gIII-ligand fusion protein that does not provide infectivity) or whether the claim is limited to embodiments where no fragment of any outersurface protein is encoded by the first vector. Alternatively, can the phrase be interpreted to mean that a vector comprising a sequence encoding multiple outer surface proteins that are functional will meet the limitations of the claim so long as at least any one surface protein coding sequence is inactivated?

Claim 1 is vague and indefinite in that there is no clear an positive prior antecedent basis for the term "the polypeptide" in part (b), lines 4 & 5.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-27, 30, 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Krebber et al (FEBS Letters, 1995, Vol. 377, pages 227-231; see the entire document).

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Krebber et al teach a filamentous phage display system where two different proteins are operatively linked to different portions of the gIII protein such that infectivity of the phage is restored upon non-covalent interaction of the two fusion proteins such that a functional gIII-chimera is displayed on the surface of the phage (e.g. Figure 1). In this construction, both of the gIII fusion proteins are encoded by the same filamentous phage. Krebber et al describe competition between multiple cognate and noncognate gIII fusions (e.g. Table 3).

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gerald G Leffers Jr., PhD

GERRY LEFFERS  
PRIMARY EXAMINER